

Applicants : Rina Aharoni et al.
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Remarks

Claims 1-46 are pending in the subject application. Claims 1-4 have been rejected, claims 16-20 and 32-39 have been allowed, and claims 5-15, 21-31 and 40-46 have been withdrawn as being drawn to a non-elected invention. By this amendment, applicants have canceled claims 1-15, 21-31 and 40-46 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in this or another application. Applicants have also added new claims 157-165. Thus, claims 16-20, 32-39 and 157-165 are now pending in this application, of which claims 16-20 and 32-39 were indicated to be allowable.

Applicants point out that this Amendment is proper under 37 C.F.R. § 1.116 because it places the subject application in condition for allowance by canceling the only claims rejected by the Examiner in the April 22, 2003 Final Office Action, i.e. claims 1-4, and non-elected claims 5-15, 21-30 and 40-46, without disclaimer or prejudice.

Support for the amendment to claim 17 may be found, *inter alia*, on page 5, lines 18-20 and page 60, lines 27-28 of the substitute specification.

Support for new claim 157 may be found, *inter alia*, on page 5, lines 18-20, page 6, lines 15-17 and page 60, lines 27-28 of the substitute specification.

Support for new claim 158 may be found, *inter alia*, on page 6, lines 26-34 of the substitute specification.

Support for new claim 159 may be found, *inter alia*, on page 6, lines 28-29 of the substitute specification.

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Support for new claim 160 may be found, *inter alia*, on page 6, lines 28-34 of the substitute specification.

Support for new claim 161 may be found, *inter alia*, on page 95, lines 9-16 of the specification as originally filed.

Support for new claim 162 may be found, *inter alia*, on page 95, lines 9-13 and 18-19 of the specification as originally filed.

Support for new claim 163 may be found, *inter alia*, on page 95, lines 9-13 and 21-22 of the specification as originally filed.

Support for new claim 164 may be found, *inter alia*, on page 95, lines 9-13 and 24-25 of the specification as originally filed.

Support for new claim 165 may be found, *inter alia*, on page 95, lines 9-13 and 27-29 of the specification as originally filed.

In the April 22, 2003 Final Office Action, the Examiner stated that, in view of applicants' January 27, 2003 amendment, the \$ 112 second paragraph rejection has been withdrawn.

In the Office Action, the Examiner also stated that, in view of the statement in the January 27, 2003 Amendment that the substitute specification contains no new matter, the substitute specification filed on January 23, 2001 has been entered.

However, the Examiner has maintained the \$ 102(f) rejection of claims 1-4.

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Claim Rejection - 35 U.S.C. § 102(f)

The Examiner maintained the rejection of claims 1-4 under 35 U.S.C. § 102(f), alleging that applicants did not invent the claimed subject matter. The Examiner alleged that the instant specification discloses on page 31 of the substitute specification and page 34 of the originally filed specification that the terpolymer consisting essentially of tyrosine, alanine and lysine randomly polymerized into a polypeptide, wherein said tyrosine is present in a mole fraction of about 0.102, said alanine is present in a mole fraction of about 0.542, and said lysine is present in a mole fraction of about 0.353 was obtained from Teva Pharmaceutical Industries, Ltd. The Examiner noted that Teva Pharmaceutical Industries, Ltd. is not an assignee, and required clarification to overcome this rejection.¹

In reply, applicants have canceled claims 1-4 without disclaimer or prejudice to applicants' right to pursue the subject matter of these claims in the future. Therefore, the rejection under 35 U.S.C. § 102(f) is moot.

For the record and in order to ensure compliance with 37 C.F.R. § 1.56, applicants note that the terpolymers which are identified on page 31, lines 11-31 of the substitute specification as having been obtained from Teva Pharmaceutical Industries, Ltd. were initially made by Dr. Alexander Gad of Teva Pharmaceutical Industries, Ltd. for use as reference standards for analytical studies of the molecular weight of glatiramer acetate. Subsequently, Dr. Gad provided samples of the terpolymers to Dr. Masha Fridkis-Hareli, who is listed as a co-inventor on this application for use in research. At that time, Dr. Gad did not

¹ The Examiner noted that applicants state that Teva Pharmaceutical Industries, Ltd. is a licensee under the subject application, but applicants had not as of the time the previous amendment was filed completed their investigation.

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conceive of pharmaceutical compositions containing such terpolymers as recited in now-canceled claims 1-4.

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

To ensure compliance with their duty of disclosure under 37 C.F.R. §1.56, applicants wish to draw the Examiner's attention to the fact that their substitute specification filed January 23, 2001, in addition to deleting certain disclosure, deleted a cross-reference to U.S. Provisional Application No. 60/123,675, filed March 9, 1999, which cross-reference was present in the originally filed specification. On August 1, 2001, applicants filed a Declaration and Power of Attorney claiming the benefit of U.S. Provisional Application Nos. 60/093,859, filed July 23, 1998, 60/101,825, filed September 25, 1998, 60/102,960, filed October 2, 1998, 60/106,350, filed October 30, 1998, and 60/108,184, filed November 12, 1998, but not of U.S. Provisional Application No. 60/123,675. A copy of PTO Form-1449 listing U.S. Provisional Application No. 60/123,675 is attached hereto as **Exhibit A**. Copy of U.S. Provisional Application No. 60/123,675 is not being submitted as this publication was previously submitted with the August 22, 2003 Amendment as Exhibit 1.

The claim to the benefit of U.S. Provisional Application No. 60/123,675 has been made in U.S. Serial No. 09/359,099, filed July 22, 1999, which was disclosed in applicants' June 26, 2002 Information Disclosure Statement in connection with the subject application. U.S. Serial No. 09/359,099 lists a different inventive entity², is assigned to a different entity³ and is prosecuted by a different attorney from the subject application. Applicants are aware of U.S. Serial No. 09/359,099 by virtue of

² Jack L. Strominger and Masha Fridkin-Harneli

³ The President and Fellows of Harvard College

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an agreement between the licensee of the subject application and the assignee of U.S. Serial No. 09/359,099.

Allowable Subject Matter

The Examiner stated that claims 16-20 and 32-39 contain allowable subject material.

Accordingly, applicants maintain that the application is now in condition for allowance and earnestly solicit a notice of allowance of claims 16-20, 32-39 and 157-165.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

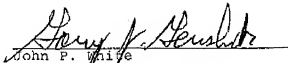
As explained above, no fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is deemed necessary, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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OCT 20 2003

OFFICIAL


John P. White
Registration No. 28,678
Gary J. Gershtik
Registration No. 39,992
Attorney for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

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ID: 212391 525

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EXHIBIT A

